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The Regulation Of Human Tissue And Regenerative Medicine In Argentina: Making Experience Work

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Policy Brief No. 4:2008

Drawing on research conducted at SCRIPT and discussions undertaken at the “Regulation of Clinical Research Involving Stem Cells: An International Workshop”, held in Buenos Aires on 29-30 November 2007, this Policy Brief places the regulation of stem cell research in the broader bioscience and health research context, highlights what have proven to be effective policy approaches in the UK, identifies some core issues in translating policy objectives into legal regulation, and offers several recommendations to facilitate the design of effective human tissue (and stem cell) regulation in Argentina (and Latin America more generally).

WHY DO THE EXPERIENCES OF OTHERS MATTER?

It is trite to confirm that there is no need to re-invent the wheel; regulatory re-invention is fruitless, not only for the time and institutional energy that it consumes, but for the real risk of repetition of mistakes that others have already made. In short, it can be entirely appropriate to examine others’ governance processes, instruments and victories/failures. Indeed, given the internationalisation of science and the (attempted) harmonisation of laws in a variety of relevant areas, not least bioethical boundary-setting and intellectual property protection, observation, adaptation and selective emulation in the regulatory field is more apt than ever before.

Jurisdictions considering regulation in the realm of regenerative medicine and human tissue use – such as Argentina – should note that many jurisdictions have developed human tissue governance regimes in an ad hoc piecemeal manner. In particular, the UK’s regime has become cumulative and complex with many competing influences. There is value in examining that system for the lessons to be learned from its lengthy legislative experience, while remaining cognizant of the particular political, economic and social/cultural settings that might influence the Argentine setting.

By doing so, Argentina can streamline its legislative process, adopting and modifying what has proven best and most effective and rejecting a priori what has proved ineffective or would be inappropriate in the Argentine context. Ultimately, the “design” of legal frameworks that can be “trusted” in other jurisdictions will facilitate the growth of Argentine science and the transport of

Regulatory re-invention can recreate the mistakes already made and may be inappropriate in a globalised setting

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its resultant products/processes.¹

WHAT ARE THE KEY FEATURES OF THE UK SYSTEM?

The UK human tissue and health innovation regimes encompass adult, fetal and cadaveric tissue use for research and/or transplantation, the use of embryos for research and treatment, and the use of body products (urine, blood, etc.) for research and/or transplantation. The regulatory landscape is populated by the Human Fertilisation and Embryology Authority (HFEA), the Human Tissue Authority (HTA), the UK Stem Cell Bank (UKSCB), the General Medical Council (GMC), the National Research Ethics Service (NRES), the Medicines and Healthcare Products Regulatory Agency (MHRA), and various (local) Research Ethics Committees (RECs), to name the most important. Commercialisation, particularly patenting, is influenced by the European Patent Convention (1973),² European legislation,³ and by decisions from the European Patent Office (EPO) and UK Intellectual Property Office (UK-IPO).

From a procedural point of view, key features of UK governance of human tissue use are:

- its reliance on statutory authorities to remove (many) decisions from the legislative arena, absorb debate and tensions, and de-politicise (to the extent possible) administration;
- its up-front approval (RECs), threshold or licensing requirements (HFEA), and on-going inspectorate functions (HFEA, HTA) to judge competence and monitor compliance;
- its relatively frequent utilisation of public consultation to test satisfaction and preferred direction of scientific and regulatory endeavour; and
- its complex and multi-actor setting.

From a more substantive point of view, key features are:

- its liberal but pragmatic and flexible approach, placing degrees of discretion in the hands of the relevant authorities to act within their sphere of competence;
- its reliance on the human rights paradigm as a legislative touchstone and its “fetishisation” of consent as a consequence thereof;
- its inability to imagine a research setting without property/ownership;
- its “pragmatic” or “loose” articulation of key underlying values (ie: its identification of the “special status” of the embryo has allowed the system

*Argentina can
modify for itself
what has proven
most
effective
elsewhere.*

*Effective UK
features include
a statutory
authority,
licensing
and public
consultation.*

1. The term “trusted” here recognises the international nature of science, production and markets, and refers to the creation of a regime that stakeholders in target jurisdictions can be satisfied will, in the usual course, result in reliable scientific outputs (ie: outputs that have been adequately ethically considered and are scientifically sound).

2. Available at www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html.

3. Directive 98/44 EC on the Legal Protection of Biotechnology Inventions, 6 July 1998, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>.

to work well for some 17 years);

- its increasing subjugation to European Union legislative influences (eg: it is estimated that 80% of regulation in the biomedical sphere comes from the EU).

Key lessons from the UK experience (not only in the human tissue context, but in the biotech context more generally) are that dialogue and clear identification of purpose deliver a reasonably good system.⁴ Open dialogue, transparent processes, clear (or identifiable) reasoning, and forthright articulation of regulatory objectives lend the eventual regulatory regime legitimacy even if disagreement over the policy-making process or regulatory content persists.

WHAT ISSUES ARE HIGHLIGHTED BY THE UK'S EXPERIENCE?

Despite generally working well, the UK's regulatory system does not currently optimise the translation of research into socially useful new technologies. Three major regulatory hurdles are:

- **Regulatory Joined-Up-ness:** There exists “innovation drag” as a result of regulatory complexities (eg: regulatory overlap and co-regulation by a variety of bodies, from the HFEA and HTA, to the UKSCB, to the GMC, the UKIPO and EPO, and more). The inefficiencies created by multiple overlapping recommendations, directions, guidance, and laws from bodies/agencies (who do not necessarily coordinate or even communicate) with an interest in different but overlapping stages of innovation, complicate and elongate the journey from idea to socially-useful output. It also makes it difficult for public actors to steer innovation derived from tissue in socially-useful directions.
- **Role of Research Ethics Committees:** A particular pressure point in the field of translating research into products/processes directed at humans is the remit and transparency of local or multi-centre RECs; more particularly, how to articulate the scope of the former and ensure the latter.
- **Access to Research Data:** There are substantial barriers to researcher/innovator access to data, and much work has been done with a view to examining the knowledge enclosure tendencies of existing intellectual property regimes.⁵

Additionally, the optimal governance of human tissue use and health innovation implicates a host of ethical challenges, some of which are currently unevenly addressed. Five core challenges are:

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4. H. Whittall, “The UK Stem Cell Research Regime”, for Argentine Ministry of Science & Technology, “Regulation of Clinical Research Involving Stem Cells: An International”, International Workshop, 29-30 November 2007, Buenos Aires.
 5. See EPO, Scenarios for the Future (Munich: EPO, 2007), which attempts to imagine possible future worlds and the place of the patent system in them. Future scenarios explored are: (1) business as the dominant driver, (2) geopolitics as the dominant driver, (3) society as the dominant driver, and (4) technology as the dominant driver.

The global setting demands regulatory joined up-ness.

- **Consent:** The imperative to obtain informed consent has become the dominant paradigm in biomedical governance, but its application to research involving health data or human tissue should be explored in more depth. Such an imperative may stand in the way of valuable regenerative medicine research and act as a hurdle to striking an optimal balance of interests. Consent is not a social value in itself, but merely a means to respect individuals; it is neither necessary nor sufficient to protect the core individual interests involved in research involving health data, viz privacy interests. Its importance for the removal of human tissue is self-evident, but its continuing role to regulate storage and use is less obvious. We suggest a frank exploration of the value and limits of consent and how its value and role may change across regulatory contexts.
- **Confidentiality:** As the UK Academy of Medical Sciences recently reported,⁶ the regulatory regime that operates within the UK with respect to privacy does not take advantage of flexibilities within the law which provide for the protection of privacy while also promoting medical research when informed consent is neither practicable nor possible. Similarly, recent work on e-health records outlines the possibilities for regulatory regimes in promoting a public interest mandate.⁷ Ultimately, a balance of public and private interests must be sought.
- **Confidence:** Public trust and confidence is crucial to effective governance and we suggest that close attention should be paid to questions of access to data, whether derived directly from medical information or indirectly from human tissue. Good governance regimes should be transparent, robust, reasonable, involve clear due process for all parties, and be subject to effective oversight. We point to the UK Biobank Ethics and Governance Council, chaired by Prof. Graeme Laurie, which is developing considerable experience in this realm; crucial to the success of the Council is a close working relationship with UK Biobank itself.
- **Commercialisation:** Our research, and that of others, has revealed some evidence of public unease about the role and consequences of commercialisation of biomedical (and particularly genomic) research.⁸ While we accept commercialisation as a reality, we suggest that the careful consideration over whether and how such public attitudes might be taken into account is necessary. Clearly, public attitudes in the UK say nothing about public attitudes in Argentina, but much can be learned from the work of centres such as ESRC/InnoGen, which have built up considerable expertise in conducting public engagement exercises.⁹
- **Collaboration:** International collaboration is essential to realising the full promise of regenerative medicine. The same is true in terms of governance, and in many ways the UK is leading the international field;

Ethical challenges revolve around consent, confidentiality, confidence, commercialisation, and collaboration.

6. Academy of Medical Sciences, Personal Data for Public Good: Using Health Information in Medical Research (2006), at <http://www.acmedsci.ac.uk/p99puid62.html>.

7. Article 29 Data Protection Working Party, Working Document on the Processing of Personal Data Relating to Health in Electronic Health Records (2007), at http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf.

8. G. Laurie et al., "Tackling Community Concerns About Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal" (2007) 64 Social Science and Medicine 272-282.

9. <http://www.innogen.ac.uk>.

once again, one can point to the UK Biobank Ethics and Governance Council, and also to the international example of the Public Population Project in Genomics (P3G), which is seeking harmonisation of efforts, both scientific and regulatory, among biobanks across the globe.¹⁰ International collaboration on access – both to data and samples – is one of the current challenges facing global scientific progress. Regulatory harmonisation – or at least mutual recognition and reciprocity – are at the heart of these debates.

WHAT ISSUES ARE APPARENT IN THE ARGENTINE SETTING?

As noted above, the particulars of the political, economic and social/cultural setting within which regulation must operate must be taken into account.¹¹ Our own research and the representations at the Regulation of Clinical Research Involving Stem Cells Workshop (Buenos Aires) expose the following as important objectives, concerns and issues in the Argentine context:

- **Leadership:** There is a desire to (1) increase the effectiveness of Argentine healthcare and thereby realise better health, (2) improve Argentine innovation pathways/systems so as to push economic growth through (health) scientific progress, and (3) to heighten the quality of Argentine science, thereby achieving international recognition and serving as a regional leader.
- **Cultural Contradiction:** Despite their widespread (and sometimes unlawful) use, reproductive technologies are highly contested and give rise to sensitive issues in Argentina, and one might expect regenerative technologies, which are closely linked thereto, to trigger similar contradictions. Although such an environment demands policy-makers to grapple with complexity and diversity, public debates over the moral status of the embryo need not necessarily be rehearsed (as they can never lead to answers or consensus). Much may be learned from the pragmatic approach adopted in the UK and its regulatory systems which emphasise scientific robustness and ethical approval mechanisms as thresholds for permitting research.
- **Regulatory Turbulence:** The existing regulatory landscape contains gaps and instabilities, including over-extension of existing regulatory bodies (such as Agencia, INCUCAI and ANMAT), insufficient communication between existing bodies, and unclear lines of authority as tissue moves between different bodies across the research field. The UK faces similar challenges, but two initiatives designed to ease the regulatory burden merit further investigation, being the Department for Business Enterprise and Regulatory Reform (BERR)¹² and the UK Clinical Research Collaboration (UKCRC),¹³ both of which are concerned with streamlining the regulatory environment.

Specific issues relevant to Argentina include leadership, cultural contradiction, regulatory turbulence, ethical concerns, and practical guidance.

10. For more on the Population Project in Genomics, see <http://www.p3gconsortium.org/>.

11. And terrible mistakes have been made by the uncritical transposition of frameworks from one socio-economic setting to another in the economic and development context: see M. Minogue & L. Cariño (eds.), *Regulatory Governance in Developing Countries* (Cheltenham: Edward Elgar, 2006).

12. www.berr.gov.uk/.

13. www.ukcrc.org/.

- **Ethical Concerns:** Regulatory turbulence contributes to ethical concerns insofar as questionable regulator remit leads to inconsistent standards and an inability to rely on what has happened under different regimes (or at different stages in the innovation pipeline), all of which gives rise to the formation of ethical grey zones.
- **Practical Research Guidance:** Scientists would benefit from clear guidance with respect to (1) the types of evidence needed before moving from one stage of a trial to another, (2) the role of placebos in trials, (3) the level of evidence required for approval of SC therapies, (4) adequate dissemination of trials being carried out,¹⁴ (5) the building of a culture of communication wherein the state, universities, research centres and scientists take an active lead. Guidance is only helpful, however, if it comes from a body with sufficient authority among the relevant regulatory players and if it provides sufficient clarity for action and responsibility; more guidance does not necessarily lead to more or better science.

RECOMMENDATIONS FOR ARGENTINA'S STEM CELL REGIME

Based on the above, we would make the following recommendations:

- **Communication and Dialogue:** It can sometimes take a long time for debates to mature; in the UK, embryonic stem cell research was preceded by the Warnock Committee's work on reproductive technologies in the mid-1980s, and evolved as the technology and moral thinking around it advanced. While such a long percolation period is not appropriate for Argentina given the advanced state of the science, a culture of communication is nonetheless essential. A discourse which incorporates hopes, actions for generating identified products and processes, and, importantly, foundational values, permits different stakeholders to offer different information/truth;¹⁵ it can promote compromise, and it does promote transparency and the commitment of resources to publicly identified purposes with clear public benefit.
- **Governance and Democratisation:** Science is not neutral; its direction and the core of its inquiries are as much a function of culture and politics as of truth. Similarly, politics and power impact on how regulation is made and therefore on the content of that regulation. Both science and regulation are most robust and responsive to public needs when they have been discussed and shaped by an informed polity. As noted above, open dialogue with stakeholders can clearly influence the direction of science and the content of its regulation. More importantly, where public-minded bodies take a lead in that dialogue, it can ensure that science and regulation is not "captured" by parochial interests. It will be important and valuable for Argentina to map the range of stakeholders, their

Lack of communication between, and inconsistent standards applied by, different regulatory institutions leads to uncertainty and innovation inefficiencies.

The value of dialogue with a variety of stakeholders cannot be underestimated.

14. The WHO has encouraged openness of information on clinical trials so that research can be linked and researchers can avoid duplication of projects (and therefore of evidence).

15. Consider the utility of social scientists "problematising" issues and investigating public perceptions around them as a means of enriching the policy dialogue and the quality, and therefore the durability, of regulation.

interests and value-preferences in order to anticipate and respond effectively when developing policy pathways in the realm of regenerative medicine and human tissue use.

- **Efficiency and Integration:** It is essential to be aware of the myriad ways in which regenerative medicine research and its regulation interacts with other existing, emerging or planned regulatory mechanisms; this promotes timely and valuable innovation. Argentina has the opportunity to map its existing regulatory pathways and to identify how more effective and efficient (or “joined up”) regulatory instruments might be developed which links innovation from idea, to basic research, to product/process development, to clinical trial, to commercialisation, to market. A single legislative framework with built-in flexibilities (to promote durability) preceded by a statement of principles may be ideal.¹⁶
- **Supportive and Creative:** There is a need for the regulatory regime to be both supportive and creative. Rather than a risk-obsessed “red light” scheme, it must be a positive, objective-oriented system which promotes a supportive environment to allow people to think creatively and innovatively within defined parameters. It must also be internally creative insofar as it links into other regimes and offers opportunities for new pathways (eg: Argentina might examine the operation of the intellectual property regime in this field and its interaction with international institutions, considering how experiments in other jurisdictions, such as the UK Stem Cell Bank’s reliance on Open Science, might be taken forward in Argentina to benefit its science sector and its public).¹⁷

Regulation must not only be about risk, but also about objectives and creating the space for good science to unfold.

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16. And it has been noted that, in the regenerative medicine research context, the regulatory instrument should apply equally to publicly and privately funded research and to publicly and privately operated biobanks, with a clear articulation of quality standards and risk issues attaching to research materials on the one hand and therapeutic materials on the other.
17. Exercises in foresight are important, but should not be extended too far or approached linearly, for innovation (and the production of regulation) is a complex undertaking with many variables. With respect to foresight, see R. Williams, “Compressed Foresight and Narrative Bias: Pitfalls in Assessing High Technology Futures” (2006) 15 *Science as Culture* 327-348.



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For more on the GET: Social Values project, visit <http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/>



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